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<b>(21) International Application Number:</b> PCT/US92/09997  <b>(22) International Filing Date:</b> 17 November 1992 (17.11.92)  <b>(30) Priority data:</b> 795,942                      18 November 1991 (18.11.91) US  <b>(71) Applicant:</b> MEDTRONIC, INC. [US/US]; 7000 Central Avenue, N.E., Minneapolis, MN 55432 (US).  <b>(72) Inventors:</b> CAMPS, Antoine, Nicolaas, Jean-Marie ; Eyserweg 36A, NL-6287 NE Eijs-Witte (NL). GRANDJEAN, Pierre, Andre ; Rue du Mari 7, B-4690 Bassenge (BE). JOHNSON, Gary, M. ; 7730-156th Avenue, N.W., Ramsey, MN 55303 (US). LEE, Philip, H., J. ; 6461 Crackleberry Trail, Woodbury, MN 55125 (US). LOKHOFF, Nicolaas, Matheus, Henricus ; Bosberg 8, NL-6464 HE Kerkrade (NL). VAN DRIEL, Willem, Johan ; Bronkstraat 6, NL-6413 DZ Heerlen (NL).		<b>(74) Agents:</b> PATTON, Harold, R. et al.; Medtronic, Inc., 7000 Central Avenue, N.E., Minneapolis, MN 55432 (US).  <b>(81) Designated States:</b> AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE).  <b>Published</b> <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> BIPOLAR TEMPORARY PACING LEAD AND CONNECTOR AND PERMANENT BIPOLAR NERVE WIRE		
<b>(57) Abstract</b>  <p>One aspect of this invention relates to a temporary heart wire, and external connector therefore, and the combination of the two, wherein the distal end of the heart wire includes a temporary affixation coil (8) and distal pacing (2) and sensing (1) electrodes connected by means of a coaxial helically wound cable (3) to a proximal electrode (7) and a breakaway needle (6) which also serves as a proximal electrode. The lead is adapted to be inserted into a disposable connector having a snap aperture element (19) for receiving the breakaway needle, and about which the needle is broken, as well as electrical contacts (17, 18) for contacting the proximal electrodes and adapted to be connected to a temporary external pacemaker. According to another aspect of this invention, there is provided a permanent bipolar nerve electrode which includes two electrodes (52, 54) adapted to be positioned along the nerve trunk (58). The bipolar nerve electrode further includes an affixation coil (56) and a thin insulation layer or flap (57), this latter being adapted to be sutured to the surface of the patient's muscle to thereby preclude or limit stimulating electrical energy to be transmitted to adjacent muscles, this allowing for a more focused concentration of electrical energy to the nerve trunk (58) to be stimulated.</p>		

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**BIPOLAR TEMPORARY PACING LEAD AND CONNECTOR  
AND PERMANENT BIPOLAR NERVE WIRE**

**BACKGROUND OF THE INVENTION**

**1. FIELD OF THE INVENTION**

5           The present invention relates to a bipolar temporary  
pacing lead which is temporarily used for post-operative  
myocardial stimulation, including pacing and sensing  
electrodes, and an affixation coil for lead anchoring as well  
as an external connector adapted for receiving the proximal  
10       end of the temporary lead. Another aspect of the present  
invention relates to a bipolar permanent nerve lead which is  
placed adjacent a nerve trunk to be stimulated including  
bipolar electrodes, an affixation coil, and an insulation flap  
for preventing unwanted transmission of electrical energy to  
15       surrounding muscle structure.

**2. DESCRIPTION OF THE PRIOR ART**

          Temporary heart wires are known in the art, for example,  
United States Patents 4,541,440 to Parsonnet and 4,341,226 to  
Peter Peters (assignee Medtronic), Temporary Lead with  
20       Insertion Tool.

          Such devices are adapted to be placed in the heart wall  
by means of a curved needle wherein the electrodes remain  
within the heart wall and the proximal end of the lead is  
brought to the exterior of the patient's chest by means of a  
25       second straight needle, located at the proximal end of the  
heart wire.

          Devices known in the prior art have drawbacks as their  
construction is somewhat primitive in that the electrodes  
constitute merely exposed portions of the conductive wire  
within the lead, no means is provided for affixing the bipolar  
30       electrodes within the heart and dislodgement is a problem, and  
the lead itself tends to be stiff as it is constructed of two

separate wires which lie in a side-by-side configuration causing stiffness in at least one direction of bending.

Also, there remains the problem of providing an external connector for the proximal end of the wire which extends externally from the patient's chest. There is a need for a convenient, easy-to-use, interface, or connector, between the lead per se and the external temporary pulse generator. Such a connector must not require substantial electrical or mechanical manipulations on the part of the surgeon, should be comfortable to the patient, and the electrical contacts must be secure and reliable. Further, the connector should be reasonably economical to manufacture, and, preferably, even disposable.

In regard to nerve wires, these wires in the past were unipolar, were more particularly adapted for implantation near nerve branches, and did not have affixation means. Further, in the prior art, no means was provided for shielding adjacent muscle structure from unwanted stimulation.

#### SUMMARY OF THE INVENTION

This invention relates to a temporary bipolar pacing lead having a proximal and a distal end wherein there are included discreet, dedicated, pacing and sensing electrode elements at the distal end as well as a coil affixation member which is integral with a plastic monofilament element connected to the curved needle.

The lead includes a coaxial wire having helicoidally wound discreet stainless steel strands providing great flexibility and excellent mechanical and electrical connecting properties.

The proximal end of the electrode includes a breakaway needle which constitutes one of the proximal electrodes with the proximal end of the lead being adapted for entry into a disposable plastic connector.

The surgeon has merely to thread the breakaway needle into the entrance aperture of the disposable plastic connector and exit the needle portion through the exit aperture. Because of the construction of the breakaway needle and the disposable plastic connector, the needle will click firmly into place within the connector housing at a fulcrum element. By closing the cover of the disposable plastic connector, a secure fixation will be made between the breakaway needle (which functions as one proximal electrode), and the other proximal electrode, with the electrical contact elements within the disposable plastic connector which are, in turn, connected to the external pacemaker. The remaining part of the needle can be removed by bending the needle, causing it to break. The broken proximal lead end will remain within the housing. In this way, a secure mechanical and electrical contact is established.

The disposable connector is preferably made of injection molded plastic, which is relatively inexpensive to manufacture, and includes an insert member on which the fulcrum and other support elements can be integrally molded.

Numerous advantages accrue to this construction and will be made apparent upon reading the more detailed description of the preferred embodiment and the claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows the heart lead constructed according to the teachings of this invention.

Figure 2 shows the lead being inserted into the myocardium of the heart.

Figure 3 shows the lead positioned within the myocardium of the heart with both distal electrodes being within the myocardium.

Figure 4 shows the lead positioned within the atrium by two passes of the curved needle resulting in the insulation being visible between the electrodes.

Figure 5 shows the removal of the curved needle from the temporary implanted lead so that the remaining part will resume its coil shape in the myocardium.

Figure 6 shows the details of the distal end of the lead.

5 Figure 7 shows details of the proximal end of the lead.

Figure 8 shows the breakaway needle.

Figure 9 shows the detail of the coaxial cable.

Figure 10 is a perspective view of the disposable plastic connector.

10 Figure 11 shows the integrally molded insert for the connector.

Figure 12 shows the integrally molded housing for the connector with cover.

Figure 13 shows the insert and cable connections thereto.

15 Figure 14 shows a top view of the connector with protective sleeves at the distal end of the leads.

Figure 15 shows a side view of the protective sleeves.

Figure 16 shows an enlarged cross sectional view of the protective sleeve positioned at the distal end of the lead.

20 Figure 17 shows the permanent bipolar nerve electrode.

Figure 18 shows a side view of the permanent bipolar nerve electrode implanted.

Figure 19 shows a top view of the insulating flap of the permanent bipolar nerve electrode.

25 Figure 20 shows a more detailed view of the permanent bipolar nerve electrode.

Figure 21 shows a more detailed view of the connector of the permanent bipolar nerve electrode.

30 Figure 22 shows an even more detailed view of the permanent bipolar nerve electrode.

#### DETAILED DESCRIPTION OF THE DRAWINGS

Figure 1 shows the bipolar temporary myocardial pacing lead constructed in accordance with the teachings of this invention.

The lead includes a curved needle (5) adapted to be used to penetrate the myocardium preparatory to drawing the heartwire and its electrodes within the myocardium.

5           The curved needle (5) is connected to monofilament strand (4) including affixation coil (8), the coil and the strand comprising one length of polypropylene, the coil insuring a good temporary fixation of the wire in the heart and prevents dislodgements which might occur with a smooth tipped lead.

10           Fixation coil (8) is connected to pacing distal electrode (2) which, in turn, is mechanically, but not electrically, connected to sensing distal electrode (1). Coil (8) and electrodes (1) and (2) are best seen in the enlarged breakout section seen in Fig. 1, and also in Fig. 6.

15           The electrodes (1) and (2) are preferably made of stainless steel which is suitable for temporary applications.

          Sensing distal electrode (1) is mechanically connected by coaxial lead wire (3) to the proximal ring electrode (7) which, in turn, is mechanically connected to breakaway needle (6).

20           Figure 2 shows the curved needle (5) penetrating the heart (9) preparatory to drawing the bipolar lead into the myocardium.

          Figure 3 shows the lead position within the myocardium with affixation coil (8), pacing electrode (2) and sensing electrode (1), being located within the myocardium of the ventricle.

25           For implantations in the atrium, the technique shown in Fig. 4 is preferred. Pursuant to the procedure of Fig. 4, the surgeon would make two passes with curved needle (5) with a portion of the lead between the pacing, or tip, electrode (2) and sensing, or ring, electrode (1) being positioned above the surface of the myocardium as shown. This particular technique is used since the wall of the atrium is much thinner than that of the ventricle and this technique safeguards against  
30  
35           accidental penetration of the myocardium.

Figure 5 shows the step in the implantation procedure whereby the surgeon cuts plastic wire (4) at the surface of the heart wall, leaving affixation coil (8) embedded in the heart wall.

5           Figure 6 shows the affixation coil and distal electrodes in a greater detail. There is seen affixation coil (8) including eight right handed wound turns.

10           The coil is crimp affixed to tip, or pacing, electrode (2) which is itself crimp connected to inner conductor filaments (10). The inner conductor filaments (10) are surrounded by inner insulation layer (11) which is mechanically connected to ring or sensing electrode (1).

15           Sensing electrode (1) is crimp affixed to the outer conductor filaments (12) which are enrobed within outer insulator layer (13).

          Figure 7 shows the proximal electrodes in greater detail. Proximal ring electrode (7) is crimp connected to the outer conductor filaments (12), being thereby in electrical contact with distal sensing electrode (1).

20           Ring electrode (7), on its proximal side, is crimp connected to the outer conductor filaments (12).

          Inner conductor filaments (10) are crimp connected to the end of breakaway needle (6), the needle thereby constituting one of the proximal electrodes and being in electrical contact with distal pacing or tip electrode (2).

25           Figure 8 shows breakaway needle (6) in greater detail. As is seen in the Figure, breakaway needle (6) includes an indentation (14) which weakens the needle at that point allowing the surgeon to snap the needle off at this point, as will be discussed.

30           Figure 9 shows the coaxial insulated wire (3) in greater detail. Inner conductor filaments (10) include 37 separate stainless steel strands each, in the preferred embodiment, each filament or wire having a diameter of 0.026 mm. Inner insulation layer (11) is made of Teflon® and covers and

35



insulates inner conductor filaments (10). Outer conductor filaments (12) include 24 stainless steel strands wound in a helicoidal manner over inner insulator layer (11), each strand having a diameter of 0.044 mm. The helicoidal winding is significant as it provides for an especially flexible construction. The outer insulator layer (13) covers the outer conductor filaments. According to a preferred embodiment, insulator (13) comprises a polyethylene coating, with the insulator being preferably color coded.

After the surgeon has positioned the lead within the myocardium, and snipped off curved needle (5), the surgeon would utilize breakaway needle (6) to pierce the thorax of the patient to bring the proximal end of the lead to the exterior of the patient's chest.

Once the proximal end of the lead is brought to the exterior of the patient's chest, it should be affixed in a suitable manner allowing for convenient, safe, connection to the external pulse generator, as well as being comfortable to the patient.

Figure 10 shows a disposable connector constructed in accordance with the teachings of this invention which is adapted functionally to interact with the aforescribed lead to produce a particularly advantageous lead-connector combination.

The connector of Figure 10 would be positioned outside of the patient's chest and, after breakaway needle (6) has been drawn through the patient's chest to the exterior, the needle is inserted into entry aperture (15) and drawn through the connector housing (16) passing over metallic electrical contacts (17) and (18), passing through flexible snap aperture (19), and finally being drawn through exit aperture (20), with the sharp end of the needle protruding from exit aperture (19) to the exterior of the connector.

The indentation in the breakaway needle discussed in connection with Fig. 8, would be drawn into snap aperture (19)

and would click firmly into place, being held by the spring action of the flexible snap aperture.

5 The disposable connector includes cover (24) adapted to be snapped down and hold firmly in place the lead, the ring electrode, and the needle. This locking feature is effected by three holding loops (25), (26), and (27), which, as seen, are generally horseshoe shaped, and which are constructed of a flexible material and have a spring action.

10 When the cover is closed, lead holding loop (25) would press against and, by its flexible spring construction, hold the lead against lead support block (21) so that movements of the patient will not disengage the lead. Similarly, ring holding loop (26) would press against and hold firmly the proximal ring electrode (7) against ring contact (17), and  
15 needle holding loop (27) would press and hold firmly the shaft of the needle (6) against needle contact (18).

20 Two cables (28) and (29) are positioned within the connector box and would be connected, respectively, to needle contact (18) and ring contact (17), these cable connections not being shown in the drawing for simplicity.

25 After the proximal end of lead (3) has been brought into the disposable connector and properly positioned, cover (24) is snap locked into the connector housing (16). This snap locking is effected by cover spring action closing loops (30) and (31) which would fit snugly into the indentations in the wall of the housing, generally indicated at (32).

30 With the indentation being held by the snap aperture (19), and the cover being closed, the surgeon would simply bend the end of the breakaway needle (6) in a horizontal direction, which would cause the needle to break at the snap aperture (19). As the snap aperture is located within the connector, there would be no sharp edge protruding to the exterior, a valuable safety feature. It will be noted that the exit aperture (20) is in the form of a horizontal slot

which allows for the bending of the needle about the fulcrum of the snap aperture.

The disposable connector and the proximal end of the lead are dimensioned to cooperate so that when the notch in the breakaway needle is positioned in snap aperture (19), the distal length of the needle will lie along, and be in electrical contact with needle contact element (18). Further, proximal ring electrode (7) will automatically lie along and be in electrical contact with ring contact element (17).

Ring contact element (17) is supported by ring support block (22) and needle contact element (18) is supported by needle support block (23). Further, there is provided lead support block (21) which is positioned under the insulated portion of the coaxial lead and which serves to hold the lead firmly within the connector, as will be further explained hereinafter.

According to a preferred embodiment, the disposable connector is made of two injection molded parts, one of these parts, the insert element being depicted in Figure 11.

This insert element would be fitted into the housing seen in Fig. 12. The snap aperture elements (19) as well as the support blocks (21), (22), and (23), seen more clearly in Fig. 11, are integrally molded with the base (32) of the insert in the sense that all of these elements constitute a single injection molded component. This insert element would then be simply inserted into housing member seen in Fig. 12, with the cover (24) ultimately being connected by a hinge (32) to connector housing (16).

Figure 13 shows in greater detail the relative positioning of external pacemaker cables (28) and (29) and the electrical contacts (17) and (18).

Figure 14 depicts a further aspect of this invention which resides in the provision of protective sleeves at the pin connectors which are adapted to be connected to an external pacemaker.

Figure 14 shows cables (28) and (29) which are adapted to be connected to an external pulse generator and which are encased in Teflon® insulation. As discussed previously, cables (28) and (29) are connected to electrical contacts (17) and (18) located in the disposable connector, which is in turn in communication with the patient's heart via the temporary bipolar heart wire.

At the distal end of the pulse generator cables (28), (29), are pin connectors (32) and tubing shanks (33) which are adapted to be connected to the pulse generator.

Protective sleeves (30) and (31) surround and electrically shield the pin connectors (32) and tubing shanks (33).

The protective sleeves (30) and (31) are made of silicon rubber.

The protective sleeves (30) and (31) are adapted to slide over the outer surface of the cables (28) and (29), thereby to expose or protect the pin connectors (32).

These protective sleeves are significant in that, when the cables (28) and (29) are not connected to a pulse generator, it is important that the cable ends be protected from any accidental electronic discharge as the cables are, as mentioned, connected directly to the patient's heart via the heart wire.

The protective sleeves (30) and (31) thus insure that the external pacemaker cables are not subject to unwanted electrical discharge or do not accidentally come into electrical contact with each other.

Figure 15 shows a side view of the external pacemaker cable (29), protective sleeve (30), pin connector (32), and tubing shank (33).

Figure 16 shows a more detailed view of the slidable protective sleeve (30), positioned around the pin connector (32) and the tubing shank (33).

As mentioned, this lead is intended for temporary use only, typically approximately two weeks. When it is time to remove the lead, the surgeon would simply pull on the lead, very carefully, and withdraw the lead from the patient's heart and chest. The affixation coil is be flexible enough to allow the heart wire to be gently pulled from the myocardium without damaging the myocardium.

According to another aspect of the invention there is disclosed a bipolar electrode which is particularly adapted for nerve stimulation.

Figure 17 shows a bipolar nerve electrode which includes a bipolar connector (50) adapted to be connected to a pulse generator.

The bipolar connector (50) is connected via coaxial cable (51) to the stimulating electrodes (52) and (54).

The outermost conductor of coaxial cable (51) is electrically connected to a first, or indifferent, electrode (52). The other, or innermost conducting wire of coaxial cable (51) itself constitutes the second electrode, the stimulating electrode (54); that is to say, stimulating electrode (54) is the exposed end portion of the internal conductor of coaxial cable (51).

The current which flows between electrodes (52) and (54) stimulates the nerve.

Positioned between the outermost conductor of coaxial cable (51) and innermost conducting wire of coaxial cable (51) is insulating sheath (53) which is made of any appropriate coaxial insulator.

As seen in Figure 17, stimulating electrode (54) is mechanically connected to a polypropylene wire (55). Polypropylene wire (55) includes affixation coil (56) which is adapted to help hold the lead in place once it has been positioned within the muscle as will be discussed hereinafter. Polypropylene wire (55) is in turn mechanically connected to insertion needle (59).

5           Positioned on the outer surface of coaxial cable (51) is an insulation layer or flap (57) which comprises a relatively thin, flat, flap or layer of silicone insulation which is preferably reinforced with dacron, such as a dacron mesh enveloped within the insulative flap (57). As will be discussed, although not seen in Figure 17, there is actually a small aperture or hole in flap (57) through which passes lead (51) which allows the flap appropriately to be positioned along the length of the lead. The flap, as seen from above in 10           Figure 17, is somewhat oval or "leaf-like" in shape. As will be discussed, as the flap is slideably connected to lead (51) only at its left hand end, the right hand end of flap (57) is free to be lifted up, away from the lead (51) and electrodes (52) and (54).

15           Current density can be changed by varying the length of the electrode (54) which increases or decreases the amount of exposed surface area of the electrode (54) which electrode is, as discussed above, the inner conductor of coaxial cable (51). This can be effected by sliding electrode (54) within 20           insulating sheath (53). Similarly, the distance between electrodes (52) and (54) could be made adjustable by sliding insulating sheath (53) within electrode (52) and within the outer conductor of coaxial cable (51). Slideability is not required as it may be that the desired exposure and distances are known at the time of manufacture and, in such case, slideability is not needed. 25           

30           According to this invention, this nerve electrode is particularly adapted to stimulate the main nerve trunk, and not the branches, of the thoraco-dorsal nerve. For such an application, the length of the stimulating electrode (54) would be approximately 0.5 cm to 1.5 cm, the length of the exposed insulating sheath (53) would be approximately 1.0 cm, and the length of the indifferent electrode (52) would be approximately 0.5 cm. The flap would be about 3.5 cm in 35           length and 2.0 cm wide.

5 In operation, the muscle is exposed by the surgeon and the bipolar nerve electrode is inserted into the exposed muscle surface by means of insertion needle (59) and positioned with the stimulating electrode (54) and indifferent electrode (52) being placed in proximity to, and in parallel with, nerve trunk (58).

10 The thin insulation layer (57) will be slid along the lead (51) and brought to the surface of the exposed muscle into which the electrodes have been inserted. As will be discussed in connection with Figure 18, flap or layer (57) is laid flat along the outer surface of the exposed muscle and is sutured about its periphery to the muscle surface.

15 By this means, when the nerve is electrically stimulated, the insulation layer (57) will function to block the electrical stimulation pulses from interfering extensively throughout the neighboring muscle structure of the patient. By virtue of this feature, therefore, the electrical energy may be applied in a more focused manner to the nerve trunk and unwanted muscle stimulation is avoided or made minimal.

20 Figure 18 shows a side view of the bipolar nerve electrode implanted into muscle (60) adjacent nerve trunk (58). There are seen electrodes (52) and (54) placed in proximity to, and roughly parallel with, main nerve trunk (58). The nerve wire is permanently held in place within muscle mass (60) by means of affixation coil (56) which remains embedded in muscle mass (60) and also by the flap which is sutured to the muscle and affixed to the cable also by suturing. The fact that the flap includes dacron reinforcement allows for good tear resistance and thus  
25  
30 permanence.

Insertion needle (59) and polypropylene wire (55) are adapted to be snipped off at the surface (61) of muscle (60) after implantation.

35 Insulation layer or flap (57) is seen in a side view positioned flat along the exposed surface (61) of the muscle.

As seen in Figure 18, the flap (57) has an aperture (62) which allows the flap (57) to slide along the surface of the coaxial cable (51).

5 When the electrodes are properly placed adjacent nerve trunk (58) and the flap (57) is properly positioned on the muscle surface (61), the outer edges of the flap (57) are sutured to the surface of muscle (61) and the flap, at aperture (62), may be glued to the coaxial lead (51) by the physician, if desired, such as by silicone glue. In this manner, the flap will rest in place on the surface (61) of the muscle (60) permanently. Further anchoring of the lead, if desired, can be accomplished by the physician suturing or otherwise securing an anchoring pledget, such as a silicone disc, to the surface of the muscle after passing the polypropylene wire through the disc.

15 Figure 19 shows a top view of the flap (57) showing the insertion aperture (62).

Figure 20 shows the bipolar nerve electrode in more constructional detail. There is seen insertion needle (59) connected to polypropylene wire (55) which is integral with affixation coil (56). The polypropylene wire is connected to the stimulating electrode (54) which includes a tip (63) connected to the coil (64) which constitutes the inner conductor of the coaxial cable (51).

25 Positioned around coil (64) is an insulating layer (57) and positioned around insulator (57) is electrode (52) which is in the form of an electrode ring.

Figure 21 shows in more detail the bipolar connector (50) connected to cable (51). This bipolar connector is adapted to be connected to a pulse generator.

30 Figure 22 shows in still greater detail the construction of the electrode portion of the nerve electrode. There is seen affixation coil (56) connected to stimulating electrode (54) which comprises tip (63) and inner coil (64). The



indifferent electrode is seen at (52) with insulating sheath at (53).

As mentioned, it would be possible to provide for adjustability of the length of electrode (54) by constructing sheath (53) to be slidable along coil (64). Alternatively, some adjustability can be obtained by simply paring away portions of sheath (53) prior to implantation so as to provide for greater exposure of coil (64).

Further adjustability could be obtained, if desired, by providing that electrode (52) be slidable over the surface of sheath (53). This would allow the distance between the two electrodes (52) and (54) to be adjusted.

While the invention has been described above in connection with the particular embodiments and examples, one skilled in the art will appreciate that the invention is not necessarily so limited and that numerous other embodiments, examples, uses and modifications of and departures from the embodiments, examples and uses disclosed may be made without departing from the inventive concepts.

CLAIMS

1. A connector for the proximal end of a temporary heart lead wherein the proximal end includes a first proximal electrode (7), and a second proximal electrode with that  
5 second proximal electrode comprising a breakaway needle (6) having along its length a point of intended breaking, the connector comprising:

a housing (16) having an entry means (15) and an exit means (20) for receiving the proximal end of said heart  
10 wire with the breakaway needle (6) in its unbroken state protruding through said exit means (20),

means for holding (19) the breakaway needle (6) at its point of intended breaking, the holding means (19) being  
15 located within said housing (16) adjacent to said exit means (20), and functioning as a fulcrum about which the needle is broken,

a first electrical contact means (17) for making electrical contact with said first proximal electrode (7) when  
the needle is held by said holding means (19),

20 a second electrical contact means (18) for making electrical contact with said breakaway needle (6) when the breakaway needle (6) is held by said holding means (19),

the first electrical contact means (17) and the second electrical contact means (18) being adapted to be  
25 connected to cables (28, 29).

2. The connector according to claim 1, wherein there is provided a cover (24) for the housing (16), and wherein there  
are included holding means (25, 26, 27) for holding the proximal end of the heart lead.

30 3. The connector according to claim 2, wherein said holding means (25, 26, 27) includes a first holding means (26) adapted to hold said first proximal electrode (7) in contact

with said first means for making electrical contact (17) and a second means for holding (27) adapted to hold said breakaway needle (6) in electrical contact with said second means for making electrical contact (18).

5           4. The connector according to claim 1, wherein there is provided an injection molded insert member (32) which fits within said housing (16) and wherein said insert member includes said means for holding (19), said means for holding being integrally injection molded with, and forming an  
10           integral part of, said insert (32).

          5. The connector according to claim 4, wherein said insert (32) further includes integrally molded support block means (22, 23) for receiving the first and second means for making electrical contact (17, 18) and further includes an  
15           integrally molded lead support block (21) for supporting a portion of the proximal end of the heart lead.

          6. The connector according to claim 1, wherein the cables (28) and (29), include, at their distal ends, electrical contact means (32), (33), adapted to be connected  
20           to an external pacemaker and wherein there is provided insulating sleeves (30) and (31) adapted to slide over the outer surface of cables (28) and (29), and, when positioned adjacent said electrical contact means (32), (33), insulate  
25           said electrical contact means (32), (33), from accidental electrical discharge or contact.

          7. A temporary bipolar heart lead for use with an external connector, the lead comprising:  
          a distal end including a sensing electrode (1), a pacing electrode (2), and an affixation coil means (8) for  
30           temporarily affixing the lead within the heart;

a proximal end including a first proximal electrode (7) and a second proximal electrode (6), the second proximal electrode comprising a breakaway needle; and

5 a cable (3) of coaxial construction interconnecting the distal end and the proximal end, the cable including an inner conductor (10) and an outer conductor (12) connecting the distal electrodes (1, 2) with the proximal electrodes (6, 7).

10 8. The lead according to claim 7, wherein the cable (3) includes a first series of inner conductor filaments (10), enrobed in a first insulating layer (11), and a second series of outer conductor filaments (12), at least said outer conductor filaments (12) being helicoidally wound.

15 9. The lead according to claim 8, wherein said first and second series of conductor elements (10, 12), are of stainless steel strands.

20 10. The lead according to claim 7, wherein the distal end of the lead includes a heart needle (5), a filament (4) of plastic material connected to the heart needle (5), and wherein the affixation coil means (8) consists of turns of plastic material which are integral with the plastic filament (4).

25 11. The lead according to claim 8, wherein the pacing electrode (2) is crimp connected to the inner conductive filaments (10) and the sensing electrode (1) is crimp connected to the outer conducting filaments (12).

30 12. The lead according to claim 11, wherein the inner conducting filaments (10) are crimp connected to the breakaway needle (6) and the outer conducting filaments (12) are crimp connected to the first proximal electrode (7).

13. The lead according to claim 12, wherein the breakaway needle (6) includes a weakened notch element (14) adapted to break when said needle is flexed about the notch element (14).

5           14. A temporary bipolar heart lead and external connector therefore, the combination including:

          a) a heart lead comprising:

                    a distal end including a sensing electrode (1),  
a pacing electrode (2), and an affixation coil means (8) for  
10 temporarily affixing the lead within the heart;

                    a proximal end including a first proximal  
electrode (7) and a second proximal electrode (6), the second  
proximal electrode comprising a breakaway needle, the  
breakaway needle having along its length a point of intended  
15 breaking; and

                    a cable (3) of coaxial construction  
interconnecting the distal end and the proximal end, the cable  
including an inner conductor (10) and an outer conductor (12)  
connecting the distal electrodes (1, 2) with the proximal  
20 electrodes (6, 7); and

          b) a connector adapted for receiving the said proximal  
end of the lead, the connector including:

                    a housing (16) having an exit means (20) for  
receiving the breakaway needle (6), which, in its unbroken  
25 state, protrudes through the exit means (20);

                    means for holding (19) the breakaway needle (6)  
at its point of intended breaking, the holding means (19)  
being located within said housing (16) adjacent to said exit  
means (20), and functioning as a fulcrum about which the  
30 needle is broken;

                    a first electrical contact means (17) for  
making electrical contact with said first proximal electrode  
(7) when the needle is held by said holding means (19);

a second electrical contact means (18) for making electrical contact with said breakaway needle (6) when the breakaway needle (6) is held by said holding means (19); and

5                   the first electrical contact means (17) and the second electrical contact means (18) being adapted to be connected to cables (28, 29).

10           15. The combination according to claim 14, wherein there is provided a cover (24) for the housing (16), and wherein there are included holding means (25, 26, 27) for holding the proximal end of the heart lead.

15           16. The combination according to claim 15, wherein there is provided an injection molded insert member (32) which fits within said housing (16) and wherein said insert member includes said means for holding (19), said means for holding being integrally injection molded with, and forming an integral part of, said insert (32).

20           17. The combination according to claim 14, wherein the cable (3) includes a first series of inner conductor filaments (10), enrobed in a first insulating layer (11), and a second series of outer conductor filaments (12), at least said outer conductor filaments (12) being helicoidally wound.

25           18. The combination according to claim 17, wherein the distal end of the lead includes a heart needle (5), a filament (4) of plastic material connected to the heart needle (5), and wherein the affixation coil means (8) consists of turns of plastic material which are integral with the plastic filament (4).

30           19. The combination according to claim 18, wherein the pacing electrode (2) is crimp connected to the inner

conductive filaments (10) and the sensing electrode (1) is crimp connected to the outer conducting filaments (12), and wherein the inner conducting filaments (10) are crimp connected to the breakaway needle (6) and the outer conducting filaments (12) are crimp connected to the first proximal electrode (7).

20. The connector according to claim 14, wherein the cables (28) and (29), include, at their distal ends, electrical contact means (32), (33), adapted to be connected to an external pacemaker and wherein there is provided insulating sleeves (30) and (31) adapted to slide over the outer surface of cables (28) and (29), and, when positioned adjacent said electrical contact means (32), (33), insulate said electrical contact means (32), (33), from accidental electrical discharge or contact.

21. A bipolar nerve electrode adapted for permanent implantation into a muscle (60) and adjacent a nerve (58) for stimulation of the nerve including:

a first (52) and a second (54) electrode means for providing opposite polarity electrical energy to the nerve (58) to be stimulated;

a cable means (52) including a conductor (54) having an exposed distal end which exposed end comprises said second electrode means (54);

an insulating means (53) positioned between said conductor (54) and said first electrode (52); and,

an insulating flap means (57) positioned at one end of said flap means to said cable means (51) for lying along a surface (61) of the said muscle (60) for shielding adjacent muscle structure from the electrical stimulation provided by said first (52), and second (54) electrodes thereby concentrating the stimulation current field to the nerve.

22. The nerve electrode of claim 21, wherein said flap means (57) is adapted to be sutured to said surface (61) of said muscle (60) and includes an aperture means (62) allowing for sliding the flap along the cable (51).

5           23. The nerve electrode of claim 21, wherein the amount of electrical energy to be applied to said nerve trunk (58) is adjustable by adjusting the length of the exposed distal end of said conductor (54) and the distance between the first electrode (52) and second electrode (54) is adjustable by  
10           adjusting the length of insulating means (53) which extends beyond said first electrode (52).

          24. The nerve electrode of claim 22, including, in combination, a guide wire (55), an affixation means (56), and an insertion needle (59), wherein the affixation means (56) is  
15           integral with said guide wire (55) and is adapted to remain permanently embedded in said muscle (60) and said guide wire (55) is adapted to be snipped off at the said surface (61) of the said muscle (60).



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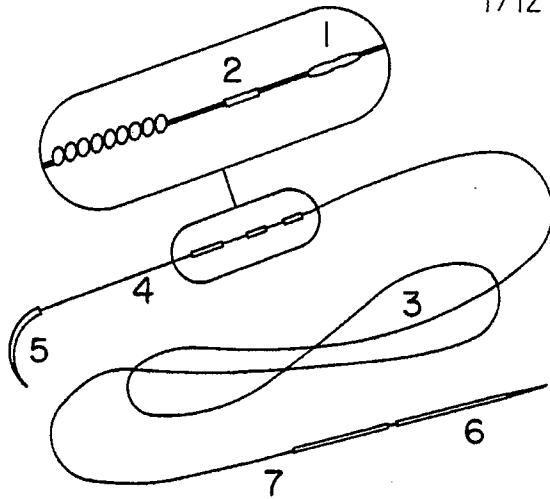


FIG. 1

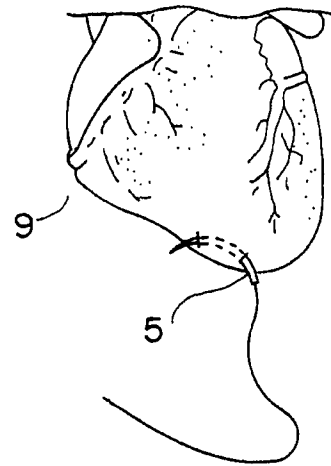


FIG. 2

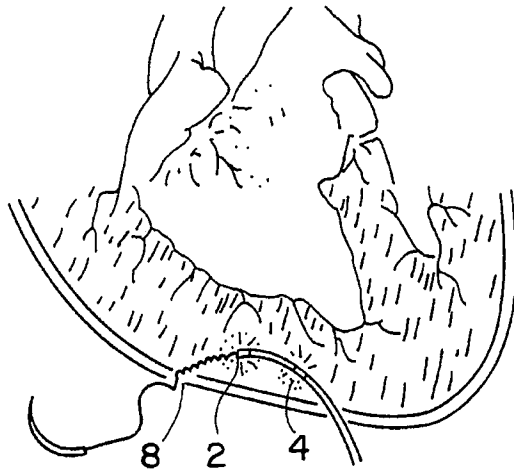


FIG. 3

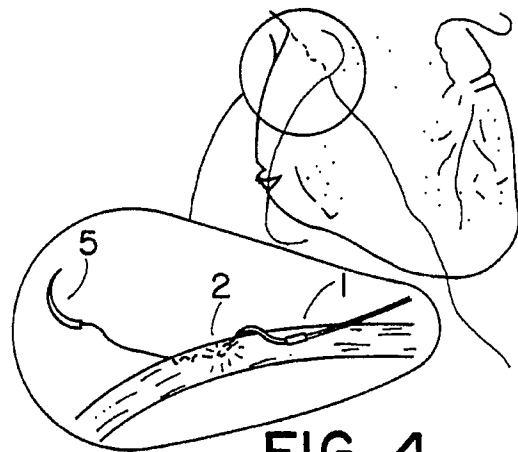


FIG. 4

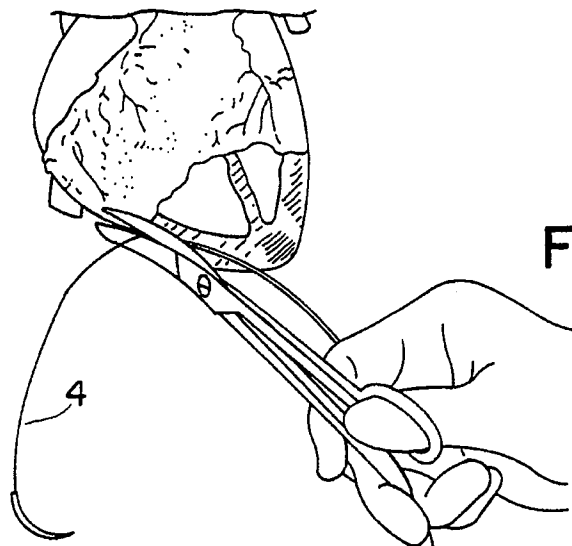


FIG. 5

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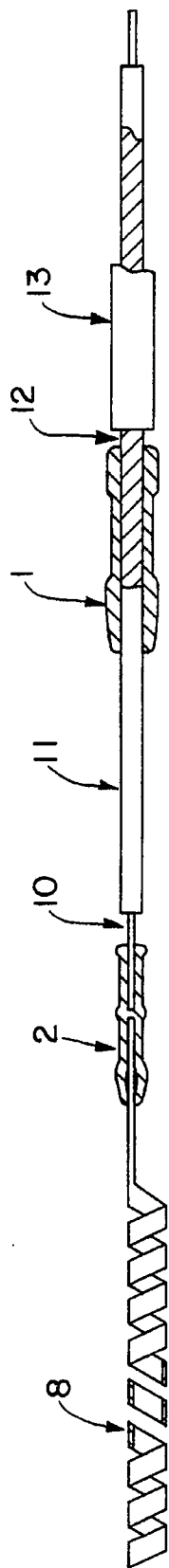


FIG. 6

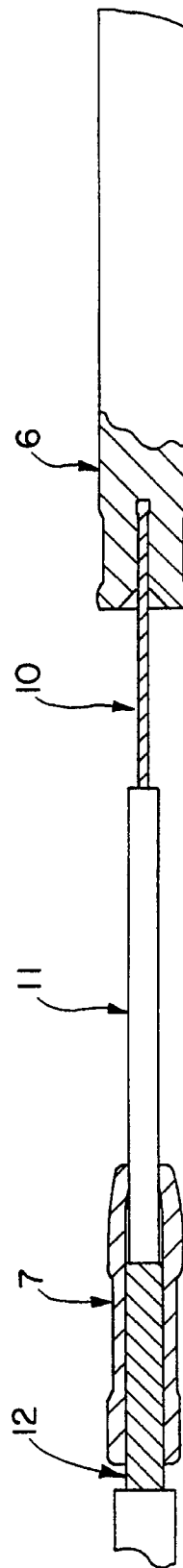


FIG. 7

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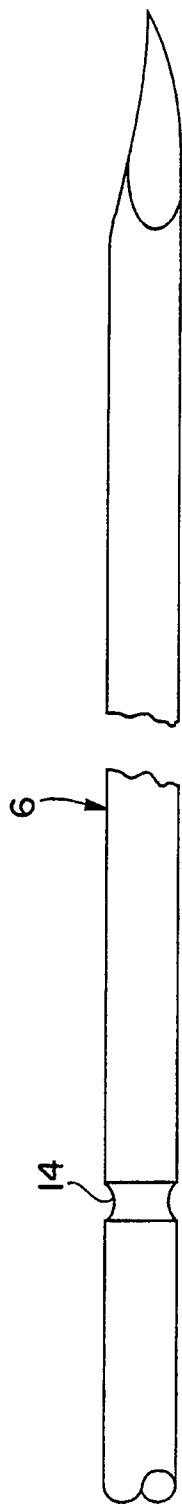


FIG. 8

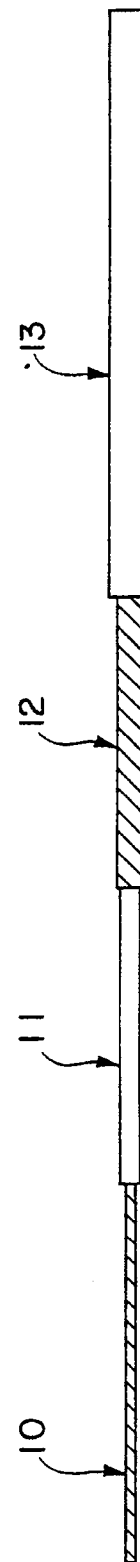


FIG. 9

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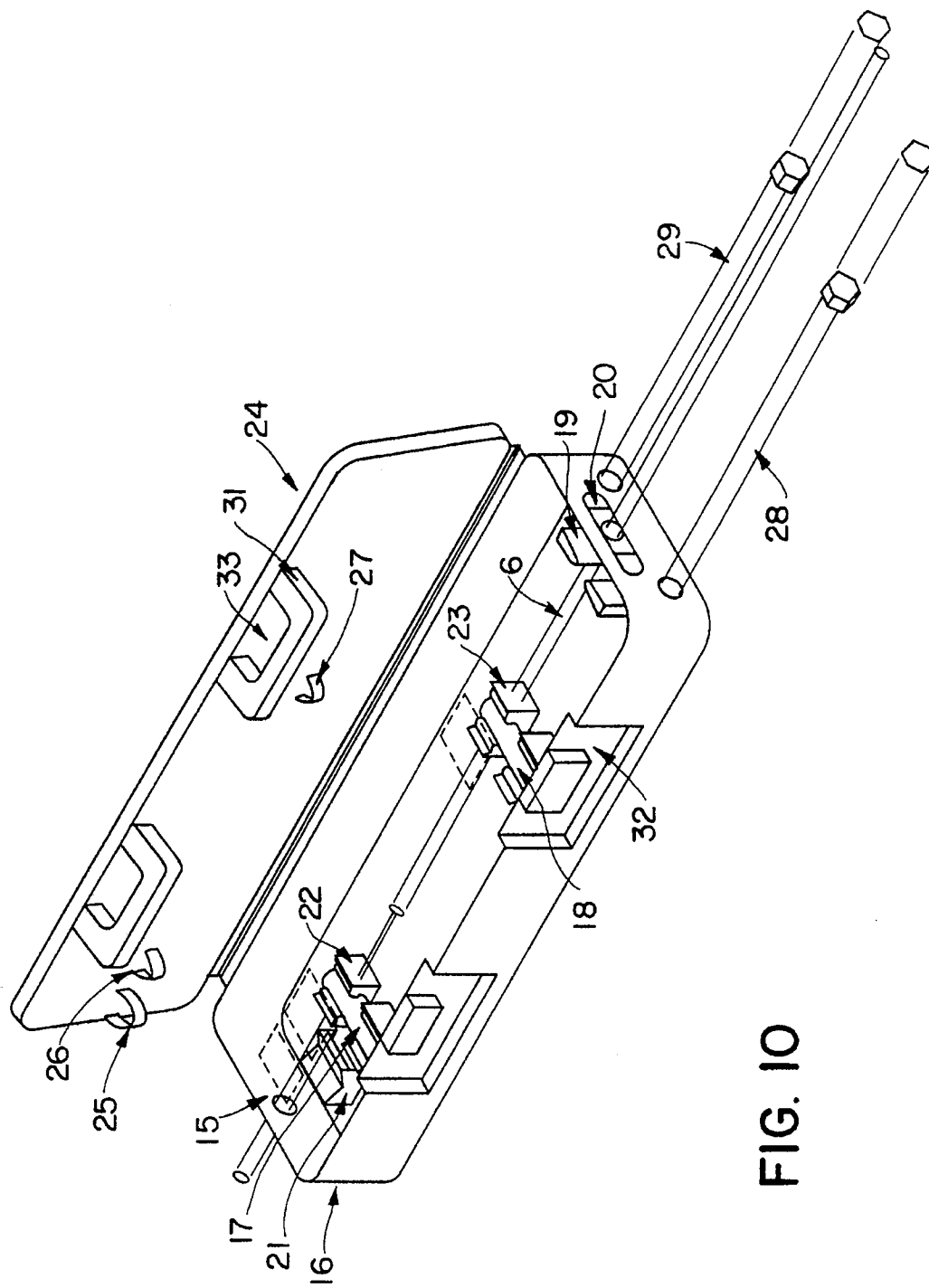


FIG. 10

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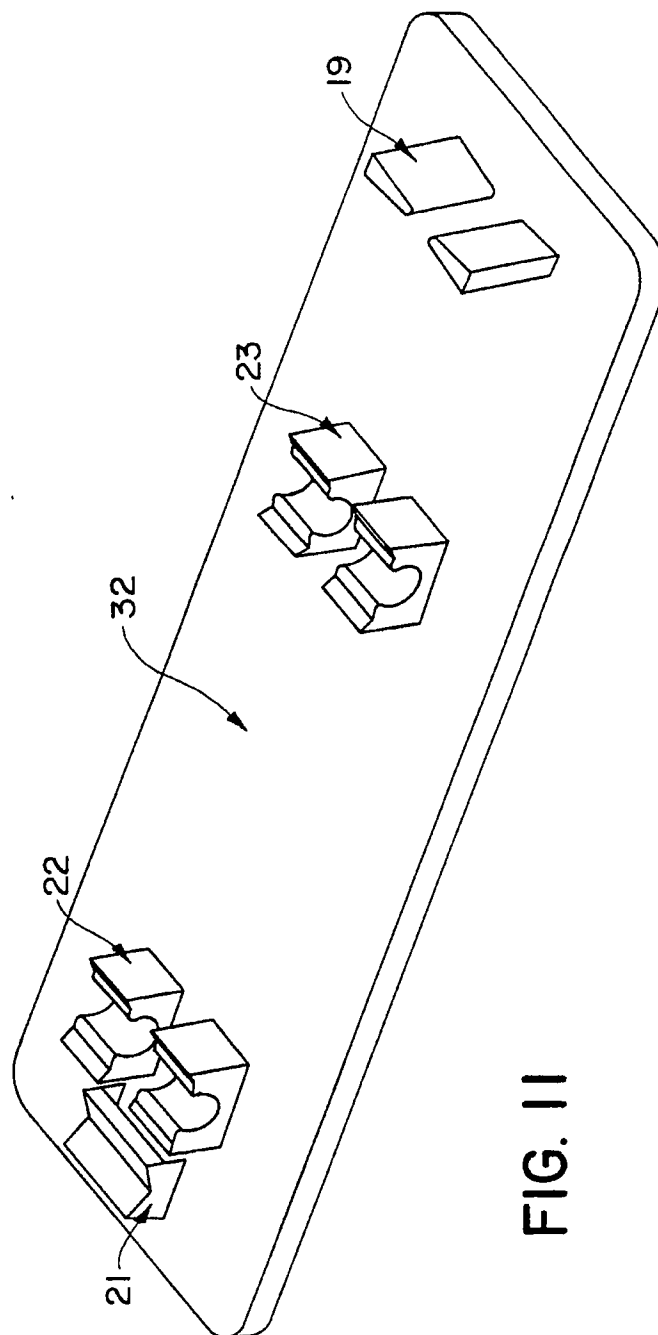


FIG. 11

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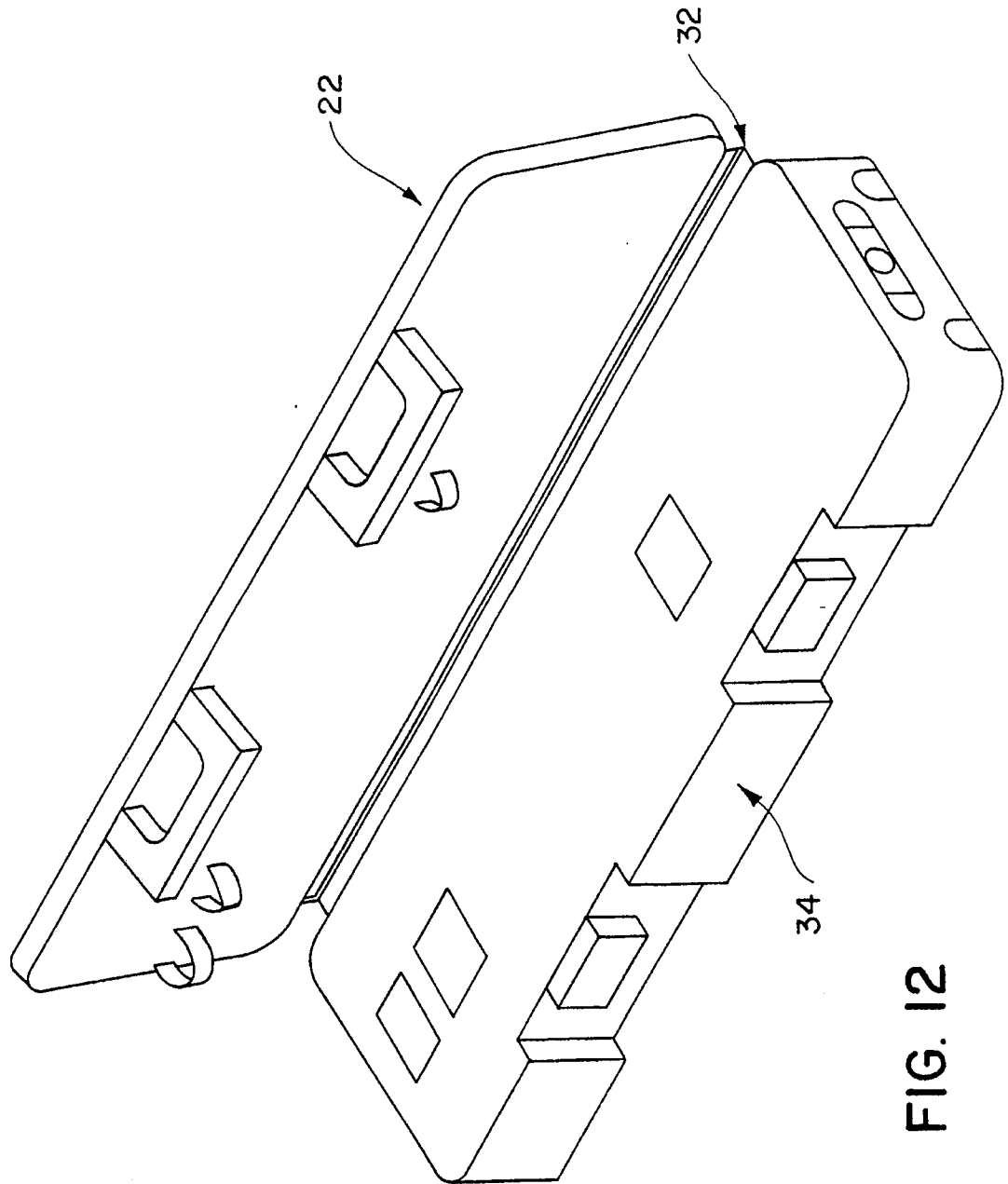


FIG. 12

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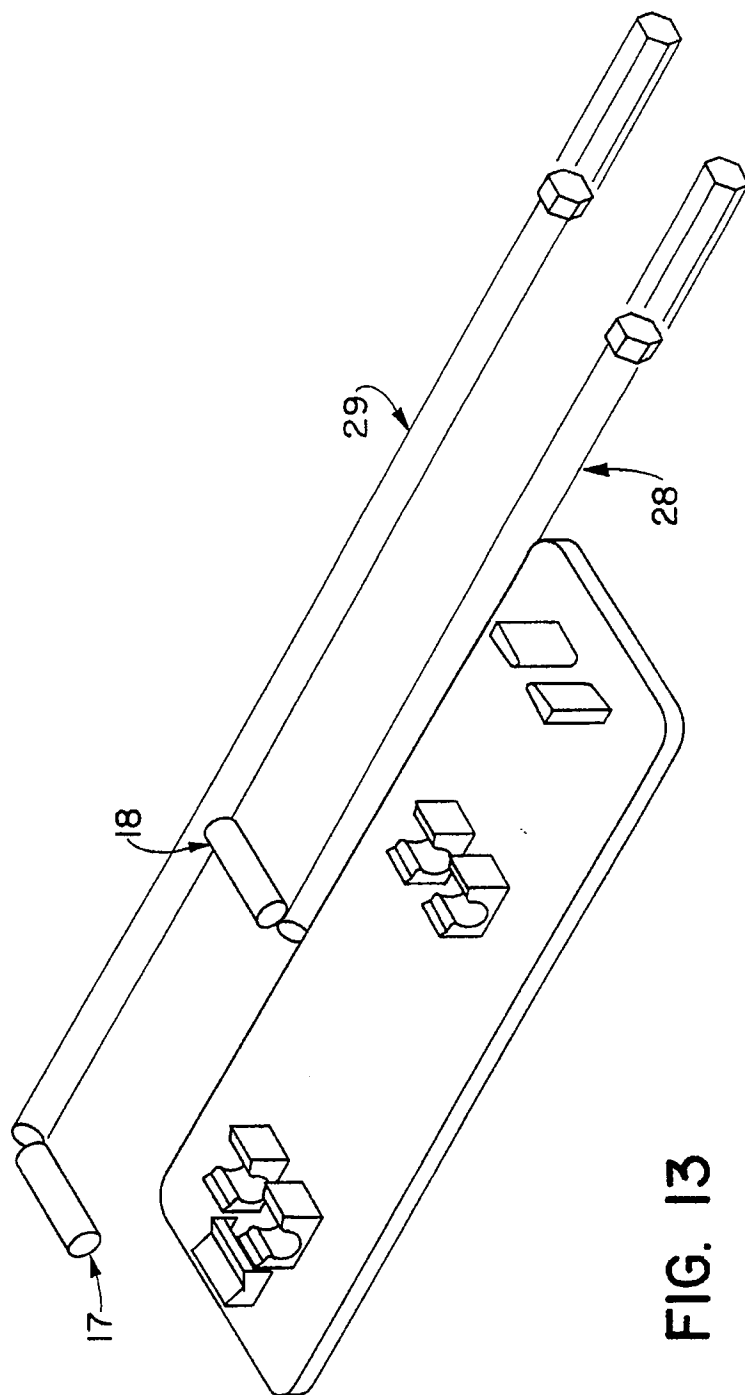


FIG. 13

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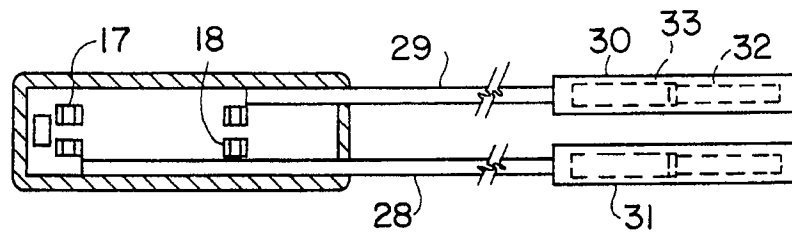


FIG. 14

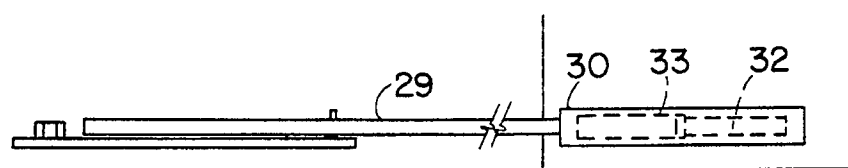


FIG. 15

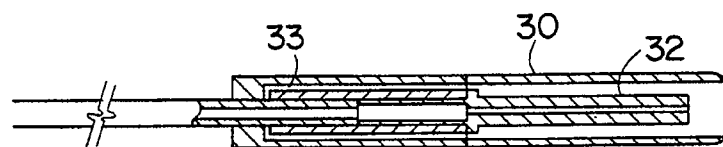


FIG. 16



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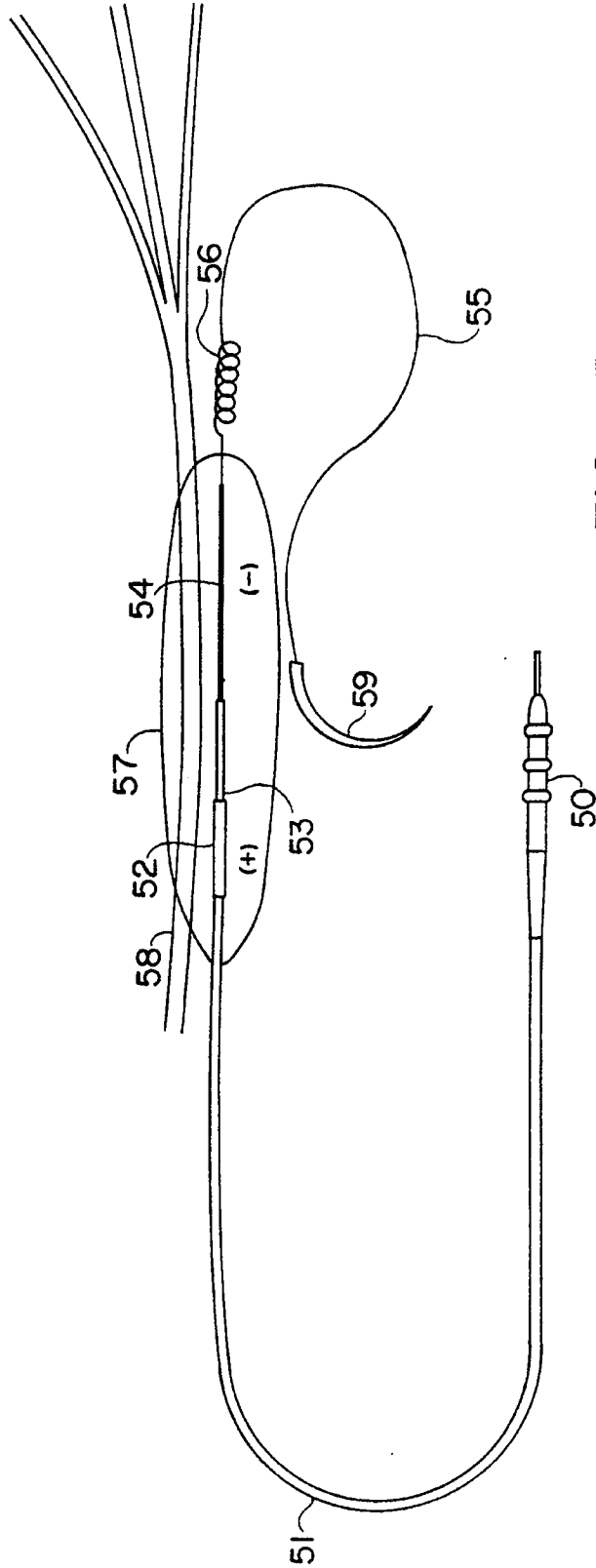


FIG. 17

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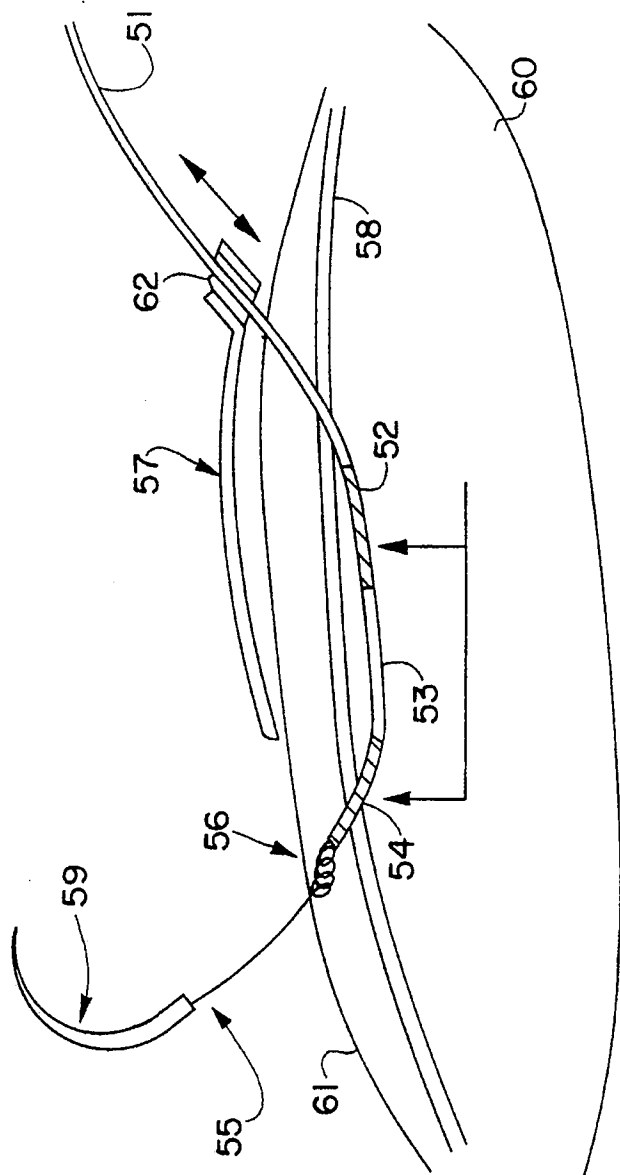


FIG. 18

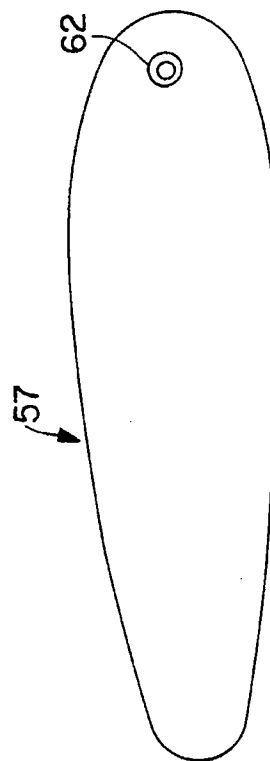


FIG. 19

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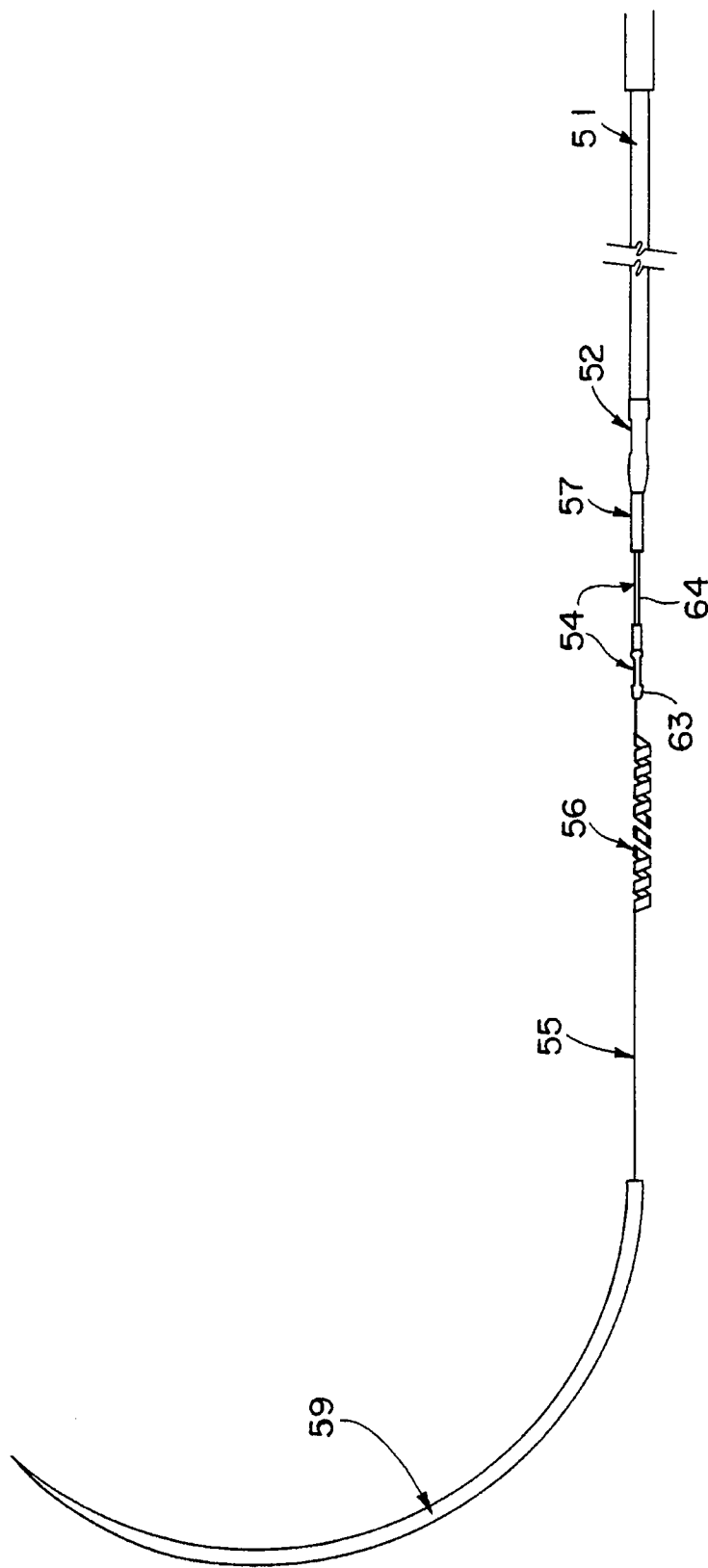


FIG. 20

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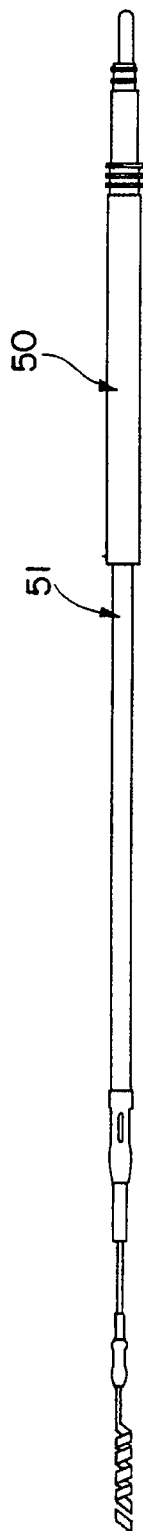


FIG. 21

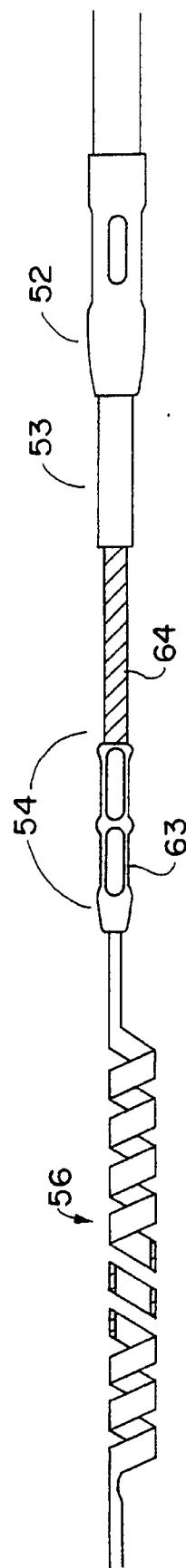


FIG. 22

## A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61N 1/05

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4541440 (VICTOR PARSONNET), 17 Sept 1985 (17.09.85), Cited in the application  --	1-24
A	US, A, 4341226 (PETER PETERS), 27 July 1982 (27.07.82), Cited in the application  --	1-24
A	DE, A1, 3412950 (OSYPKA, PETER), 17 October 1985 (17.10.85), figure 1, abstract  --	1-24

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

## \* Special categories of cited documents:

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- "O" document referring to an oral disclosure, use, exhibition or other means
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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

3 March 1993

25.03.93

Name and mailing address of the ISA/  
European Patent Office, P.O. 5818 Patentaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3016

Authorized officer

Rune Bengtsson

## INTERNATIONAL SEARCH REPORT

international application No.

PCT/US 92/09997

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE, C2, 2605637 (ETHICON, INC.), 11 October 1984 (11.10.84), figures 1-4  --	1-24
A	US, A, 4136703 (FREDERIK H.M. WITTKAMPF), 30 January 1979 (30.01.79), See the whole document  -- -----	1-24

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## INTERNATIONAL SEARCH REPORT

Information on patent family members

29/01/93

International application No.

PCT/US 92/09997

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US-A- 4341226	27/07/82	NONE	
DE-A1- 3412950	17/10/85	DE-A- 3565777 DE-U- 8410768 EP-A,B- 0159540 US-A- 4633880	01/12/88 07/05/86 30/10/85 06/01/87
DE-C2- 2605637	11/10/84	BE-A- 838351 CA-A- 1062339 FR-A,B- 2300580 GB-A- 1517453 US-A,B- 4010756	06/08/76 11/09/79 10/09/76 12/07/78 08/03/77
US-A- 4136703	30/01/79	EP-A,B- 0009530	16/04/80